IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

NATURAL RESOURCES DEFENSE COUNCIL, INC., Plaintiff, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., Defendants.	)	10 Civ. 5690 (AKH) (AJP)

PLAINTIFF'S REPLY IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT AND OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

Thirty-seven years ago, the FDA proposed to regulate two chemicals, triclosan and triclocarban, which are found in over-the-counter antimicrobial soaps and handwashes. Through several rounds of proposed rulemaking during the intervening decades, the agency maintained its tentative classification of these chemicals as either unsafe or ineffective, or lacking adequate proof of safety and effectiveness. Since 1974, when the FDA's advisory panel first expressed concern over potential organ damage resulting from long-term exposure to the chemicals, consumer and health-care personnel products containing these ingredients have proliferated on the market. Meanwhile, mounting medical evidence suggests that triclosan and triclocarban may have deleterious endocrine-disrupting effects and contribute to the development of antibiotic-resistant "superbugs." Against this backdrop of risk to human health, and despite the agency's recognition that these products are no more effective than regular soap and water, the FDA refuses to commit to a deadline for finalizing regulation of triclosan and triclocarban.

Judicial intervention is essential to end this decades-long regulatory snarl. The FDA's assertion that the antimicrobial drug review process is complex and entails consideration of polarized interests fails to justify the extraordinary length of its delay. A court order directing the agency to decide by a date certain whether or how to regulate triclosan and triclocarban will effectuate Congress's dual command that the FDA (1) protect public health by prohibiting the marketing of drugs not proven to be safe and effective and (2) fulfill this statutory duty with reasonable speed. *See* 21 U.S.C. § 355 (Federal Food, Drug, and Cosmetic Act); 5 U.S.C. §§ 555(b), 706(1) (Administrative Procedure Act).

ARGUMENT

NRDC has standing to challenge the FDA's inaction on behalf of its members who have a reasonable apprehension of health harm from their exposure to triclosan- and triclocarban-containing products. The agency's argument that this injury is avoidable through the use of substitute soap products, and is thus too speculative, ignores the facts and is unsupported by case law. NRDC's members are at times involuntarily exposed to triclosan and triclocarban. Moreover, the government's theory of standing would compel consumers to choose between attempting to minimize their risk of harm and asserting their statutory rights. The law does not demand this choice. NRDC's members suffer a concrete, cognizable injury that is directly traceable to the FDA's delay in regulating triclosan and triclocarban, and a finalized drug monograph establishing conditions of use for these chemicals ("Monograph") will redress this harm.

The reasonableness of the FDA's delay is measured against multiple factors, including the goal of the Federal Food, Drug, and Cosmetic Act (FFDCA) to remove unsafe and ineffective drugs from the market. While regulatory complexities and competing agency priorities are to be taken into account, these justifications are insufficient after three decades—and counting—of delay. The FDA first proposed regulating triclosan and triclocarban in 1974, and through successive rounds of tentative Monographs, the agency consistently expressed its belief that there was insufficient evidence to establish the chemicals' effectiveness and safety. Yet the agency has permitted the chemicals to remain on the market. The delay in finalizing the Monograph has proven self-perpetuating. While the agency continues to withhold a final decision, the use of triclosan- and triclocarban-containing products in home and health-care settings has increased, and new science pertaining to their harmful health effects has emerged. If

justifications of evolving scientific knowledge and regulatory difficulties are sufficient to excuse thirty-seven years of delay, then there is no certainty that the FDA will ever finalize the Monograph. Meanwhile, consumers continue to suffer increased risk of harm from their long-term, aggregate exposure to triclosan and triclocarban.

I. Apprehension of the Adverse Health Impacts of Triclosan and Triclocarban Exposure Is a Cognizable Injury Redressable by FDA Action

A. NRDC's Members Allege an Injury in Fact

NRDC's members suffer an injury in fact based on their fear of health harms arising from cumulative exposure to triclosan and triclocarban. *See* Schwarzman Decl. ¶¶ 12, 14 (discussing her desire to "avoid any unnecessary exposure" because even "exposure in small amounts can potentially have serious effects"); Owens Decl. ¶¶ 5, 9, 12-18 (discussing her health concerns and exposure to triclosan-containing products at work). The FDA challenges this basis for standing, claiming that the purported ability of plaintiff's members to bring their own soap to work or to use alcohol-based sanitizers relegates their injury to the realm of the hypothetical. Defs. Br. at 34-37. This argument is contrary to the law of the Second Circuit and other courts, under which plaintiffs do not sacrifice the opportunity to assert statutory rights merely because they may be able to alter their behavior to avoid an injury. *See, e.g.*, *Baur v. Veneman*, 352 F.3d 625, 628 (2d Cir. 2003) (finding that the plaintiff, who consumed beef, had standing to challenge meat safety regulation); *Pub. Citizen v. Foreman*, 631 F.2d 969, 974 n.12 (D.C. Cir. 1980) (noting that the plaintiffs had a cognizable injury regarding food additive despite availability of substitute products).

NRDC members' apprehension over their exposure to triclosan and triclocarban is concrete and not "hypothesized." The veterinary clinic where Ms. Owens works supplies antibacterial hand soap, lotion, and dish soap, all of which contain triclosan. Owens Decl.

¶ 13. In the course of inspecting animals, taking blood samples, and growing lab cultures, Ms. Owens washes her hands more than fifty times a day, which repeatedly exposes her to triclosan. *Id.* ¶¶ 12, 14. Contrary to defendants' assertion, Ms. Owens has raised her concern with her supervisor, but to no avail. *Id.* ¶ 18 ("I have discussed my concern about triclosan exposure with the clinic owner . . . but because [the owner] do[es] not really know about the health risks, nothing is done to limit our exposure."). Dr. Schwarzman similarly lacks control over her exposure to triclosan at the hospital where she completed her residency and currently works. Schwarzman Decl. ¶¶ 4-5, 8-9. Both members also fear the potential harm to their family members from exposure to antimicrobial products containing triclosan. Owens Decl. ¶¶ 5, 19, 21 (discussing concern over her husband's and five-year-old nephew's health); Schwarzman Decl. ¶ 12 (expressing desire to reduce exposure to triclosan and triclocarban during her childbearing years). Although Ms. Owens and Dr. Schwarzman have taken steps to avoid use of antibacterial products at home, they are harmed by their exposure at work. Their concerns about each incremental exposure to triclosan and triclocarban are reasonable, and the FDA itself has credited these concerns. *See* Janssen Decl. ¶ 30; FDA Letter to Markey, Ex. 11 to Wang Decl., at 2 ("It is FDA's opinion that existing data raise valid concerns about the effects of repetitive daily human exposure to these antiseptic ingredients.").

The possibility that members could bring their own soap and lotion to work, Defs. Br. at 37, does not deprive plaintiff of standing. As an initial matter, veterinary clinic and hospital policies may prohibit employees from using sanitizing products from outside the workplace. And even if NRDC's members could purchase triclosan-free products for work, the availability of alternatives does not render their injury conjectural. Defendants' theory of avoidable harm would eviscerate standing for most environmental and health-related claims, because a plaintiff

could always choose not to use a polluted river or consume a certain food or drug. This is contrary to law. *See Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 181-84 (2000) (finding injury in fact based on plaintiffs' concern about mercury discharges, which led them to modify their behavior by not recreating in or near a river).

In cases alleging violation of food and drug safety laws, courts have declined to require that plaintiffs demonstrate an inability to modify behavior to avoid the harm. In *Baur v. Veneman*, the Second Circuit considered a challenge to the FDA's decision not to regulate "downed" livestock as adulterated food. 352 F.3d at 628-29. The court found that the plaintiff's "apprehension and concern arising from [the] risk" of eating beef contaminated with BSE ("mad cow") disease was a cognizable injury. *Id*. at 630. The D.C. Circuit addressed a similar claim of injury in *Public Citizen v. Foreman*, where a public interest group sought an injunction compelling the FDA to regulate sodium nitrite as an unsafe additive in bacon. 631 F.2d at 971. The court rejected the government's challenge to the plaintiffs' standing, concluding that even though the plaintiffs "could abstain from eating bacon entirely or seek out the nitrite-free bacon that may be available, it is an injury nonetheless." *Id.* at 974 n.12 (citation omitted); *accord Cutler v. Kennedy*, 475 F. Supp. 838, 850 (D.D.C. 1979) (stating that increased risk of exposure to unsafe or ineffective drugs would not be alleviated by "a decision to forego the use of OTC drugs altogether"), *rev'd in part on other grounds*, *Chaney v. Heckler*, 718 F.2d 1174, 1188 (D.C. Cir. 1983); *see also Barnes v. Shalala*, 865 F. Supp. 550, 560 (W.D. Wis. 1994) (finding that consumers of dairy products had standing to challenge the FDA's approval of bovine growth hormone and noting that even if voluntary labeling by milk distributors would alleviate some of plaintiffs' concerns, the "complete cure for plaintiffs' injury" would be a change in FDA's decision).

The FDA also claims that NRDC's members do not suffer a concrete injury because NRDC's website, which provides information about alternatives to triclosan-containing products, demonstrates that members can avoid the alleged harm. *See* Defs. Br. at 34-35. The availability of alternatives in the market is immaterial because plaintiff's members lack control over exposure to triclosan-containing products in their workplaces. *See* Owens Decl. ¶¶ 12-14, 18; Schwarzman Decl. ¶¶ 8-9. Despite efforts to limit exposure at home, Ms. Owens's and Dr. Schwarzman's contact with these chemicals in other settings is sufficient for standing. As the Second Circuit has observed, injury in fact is based on a qualitative analysis, not a quantitative calculation of degree of risk. *Baur*, 352 F.3d at 637; *see also United States v. Students Challenging Regulatory Agency Procedures (SCRAP)*, 412 U.S. 669, 690 n.14 (1973) ("Injury in fact . . . serves to distinguish a person with a direct stake in the outcome of a litigation-even though small . . . an identifiable trifle is enough for standing . . . ." (internal citations and quotation marks omitted)).

The cases the agency relies on are distinguishable. In *Coalition for Mercury-Free Drugs v. Sebelius*, the plaintiffs failed to demonstrate any harm from the delay resulting from visiting a different pharmacy to obtain a mercury-free vaccine. No. 09-0015 (RBW), 2010 WL 2889182, at *6-*7 (D.D.C. July 1, 2010). None of the plaintiffs in that case alleged that she had received a vaccine based on misinformation about the mercury preservative, and the injunctive relief requested would not redress health harms that had already occurred. *Id.* at *7-*8. In contrast, NRDC members allege harm from ongoing, involuntary exposure to triclosan-containing products, and the delayed finalization of the Monograph prolongs their contact with these chemicals. *See* Janssen Decl. ¶ 36. Because these potential endocrine disruptors have health effects at low concentrations, even if some members can limit exposure at home, their

exposure at work can "potentially have serious effects." Schwarzman Decl. ¶ 14; *see also* Janssen Decl. ¶ 30.

The harm to plaintiff's members is concrete and more than "mere disagreement" with government policy or "interest in a problem." *See* Defs. Br. at 31-32 (citing cases). In *Center for Law & Education v. Department of Education*, the plaintiffs claimed that a federal rule giving states discretion to implement education policies might result in improper classification of their children's schools. 396 F.3d 1152, 1160-61 (D.C. Cir. 2005). The court found this harm too attenuated because it hinged on the independent choices of a third party, the states. *Id.* at 1161. In contrast, NRDC's members are directly harmed by exposure to products that are within the FDA's regulatory ambit. *Korsinsky v. EPA* is also inapposite because the plaintiff's physical injury (that over time, global warming would increase the risk of drinking water contamination) was too conjectural to meet the standard of *Baur*, and his mental injury (apprehension of harm from the general dangers of pollution) would not be redressed by holding the defendants liable for carbon dioxide emissions. No. 05 Civ. 859 (NRB), 2005 WL 2414744, at *2-*3 (S.D.N.Y. Sept. 29, 2005). The *Public Citizen* case cited by the FDA relies on a particular test for probabilistic harm that has not been adopted by this Circuit. *Pub. Citizen, Inc. v. Nat'l Highway Traffic Safety Admin.*, 513 F.3d 234 (D.C. Cir. 2008). In that case, the court found that the plaintiffs lacked standing because they failed to present data showing an increased risk of harm from the agency's tire pressure monitoring rule compared to one of plaintiffs' proposed alternatives, which was to require automakers to provide a list of tires compatible with the under-inflation warning system. *Id.* at 237. Here, in contrast, NRDC's members are injured by their apprehension over the potential health harms resulting from each increment of actual exposure to triclosan and triclocarban, and their reasonable

concern provides a basis for standing. *See, e.g., N.Y. Pub. Interest Research Group v. Whitman*, 321 F.3d 316, 325 (2d Cir. 2003) (finding injury despite plaintiffs' uncertainty over extent of exposure to air pollutants); *LaFleur v. Whitman*, 300 F.3d 256, 270-71 (2d Cir. 2002) (holding that plaintiff who lived close to a proposed facility had standing based on her exposure to increased sulfur dioxide emissions, even if those emissions would be well below federal limits designed to protect public health).

B. Plaintiff's Injury Would Be Redressed by FDA Action Finalizing the Monograph

The harm alleged in this case is directly traceable to the FDA's inaction. A court order compelling the FDA to finalize the Monograph by a date certain would redress plaintiff's injuries: The agency would either (1) classify triclosan and triclocarban as Category II or III ingredients, resulting in their removal from the market, or (2) classify them as Category I ingredients, representing an agency determination that the products are safe and effective. Under the first scenario, plaintiff's members would no longer be exposed to antimicrobial products containing triclosan and triclocarban. And under the second scenario, members' concerns would be alleviated by a well-reasoned FDA determination of safety and they could tailor their behavior accordingly, for example, by not purchasing triclosan-free soaps that are harder to find or more expensive. *Cf. Me. People's Alliance v. Mallinckrodt, Inc.*, 471 F.3d 277, 283 n.5 (1st Cir. 2006) (finding that plaintiff's injury would be redressed by court-ordered study of mercury contamination, which would permit plaintiffs to adjust their usage of the river based on its contamination level, whether or not the study found endangerment from the mercury).

Unlike the plaintiff in *Gettman v. Drug Enforcement Administration*, who claimed that the agency decision not to reclassify marijuana prevented him from offering his research

services, relief in this case does not depend on the actions of third parties. 290 F.3d 430, 434 (D.C. Cir. 2002) (noting that even if the DEA granted the requested relief, it did not mean that customers would seek out the plaintiff's consulting services). The FDA's statements regarding the market pricing and availability of triclosan-free products, Defs. Br. at 36 n.11, are therefore irrelevant.

* * *

Plaintiff's claim of cognizable injury is reinforced by the "tight connection between the type of injury" alleged and "the fundamental goals of the statute[] which [it] sues under"—the "very purpose of the . . . FFDCA . . . [is] to minimize the risk to public health from potentially dangerous food and drug products." *Baur*, 352 F.3d at 634-35. FDA's thirty-seven year delay in finalizing its regulation of antimicrobial products is an abdication of its statutory duty to minimize the "risk of exposure to unsafe or ineffective drugs," and the relief requested would redress this harm. *See Cutler v. Kennedy*, 475 F. Supp. at 850. Plaintiff has standing to sue.

II. The Delay in Regulating Triclosan and Triclocarban Is Unreasonable in Light of FDA's Acknowledgment of the Drugs' Ineffectiveness and Potential Health Risks

The agency offers six specific justifications for its decades-long delay in finalizing the Monograph. Defs. Br. at 30-53. It asserts that (A) the review process for OTC drugs in general, and antimicrobial products in particular, has been more complex than anticipated, involving numerous active ingredients, conflicting public comments, and evolving medical knowledge; (B) there is no fixed regulatory deadline for a final decision; (C) there is insufficient evidence of harmful consequences from delay; (D) competing priorities vie for the agency's attention; (E) NRDC's interests are not prejudiced by continued postponement of a decision; and (F) the delay is not the result of agency impropriety. NRDC refutes these arguments in turn.

A. Regulatory Complexity, Inherent in All Science-Based Rulemaking, Does Not Excuse Lengthy Delay in Protecting Public Health

The FDA argues that the pace of its work on the Monograph has been reasonable in light of the difficulty of the task. In determining the reasonableness of the FDA's inaction, the complexity of the OTC drug review process must be balanced against the extraordinary length of delay and the potential for harm arising from the delay. *See Cutler v. Hayes*, 818 F.2d 879, 898 (D.C. Cir. 1987). Here, the balance tips against the agency. The FDA's continuing failure to finalize the Monograph prolongs the threat to human health from chemicals that have not been established as safe and effective. Under these circumstances, the "complexity of the task confronting the agency" is insufficient to justify delay. *See id.*

The FDA's brief sets forth the multiple stages of OTC drug review and the agency's decision to create additional subcategories of product uses in its evaluation of antimicrobial drugs. *See* Defs. Br. at 15-17. However, the "size and complexity" of the antimicrobial review process, *id.* at 15, is not unique or confined to this subset of agency action. Rulemaking necessarily entails balancing competing interests of industry and consumers and is often conducted within the dynamics of evolving scientific and technical knowledge. *See, e.g., In re Int'l Chem. Workers Union*, 958 F.2d 1144, 1149, 1150 (D.C. Cir. 1992) (acknowledging "complex scientific and factual data" at play in OSHA rulemaking but concluding that six-year delay in promulgating standard for occupational exposure to cadmium had been "too lengthy for us to temporize any longer"); *California v. FCC*, 905 F.2d 1217, 1231 (9th Cir. 1990) (describing economic and technical complexity of FCC rule on enhanced data processing networks); *Lead Indus. Ass'n, Inc. v. EPA*, 647 F.2d 1130, 1184 (D.C. Cir. 1980) (describing complex scientific and technical issues involved in setting national ambient air quality standards for lead). But if the rationale of complexity were sufficient to excuse delay, this

would undercut the command of the Administrative Procedure Act that each agency "conclude a matter presented to it" within "a reasonable time." 5 U.S.C. § 555(b).

Examples of prior regulation supplied by the FDA's declarant, Dr. Ganley, demonstrate that scientific uncertainty and the need to consider conflicting public comments do not prevent the agency from reaching final decisions on OTC drug regulation. The agency published a proposed regulation for antiperspirants containing zirconium in 1975. 40 Fed. Reg. 24328 (June 5, 1975), Ex. 9 to Ganley Decl. Two years later, after granting a request by the product manufacturer for an extension of the comment date "for compilation of extensive new data" regarding potential toxicity, the FDA removed zirconium products from the market "[b]ecause it appears that conclusive testing . . . would take years to accomplish." 42 Fed. Reg. 41374, 41374, 41376 (Aug. 16, 1977), Ex. 13 to Ganley Decl. The agency took final action despite finding that the data were "incomplete" and that the "issue of long-term toxicity remains unresolved." *Id.* at 41374. Similarly, in banning the antimicrobial agent hexachlorophene within a year of proposed rulemaking, the FDA evaluated "[r]ecent data" regarding the ingredient's toxicity against "long years of use" and analyzed more than 250 comments, including statements that human toxicity studies were still emerging and that it was "unreasonable to extrapolate quantitative levels of toxicity from other species to man." 37 Fed. Reg. 20160, 20160-61 (Sept. 27, 1972), Ex. 5 to Ganley Decl.

Courts have rejected agency claims that regulatory and scientific complexities justify delayed regulations concerning human health. The D.C. Circuit has compelled agency action to limit worker exposure to cadmium, *In re Int'l Chem. Workers Union*, 958 F.2d at 1149, to protect coal miners from exposure to diesel emissions, *In re United Mine Workers of Am. Int'l Union*, 190 F.3d 545, 554 (D.C. Cir. 1999), and to set a standard for industrial exposure to

ethylene oxide, *Pub. Citizen Health Research Group v. Auchter*, 702 F.2d 1150, 1159 (D.C. Cir. 1983). In all of these cases, the court dismissed the agency's arguments, similar to the ones made by the FDA here, regarding limited personnel resources and the difficulty of the regulatory task at hand. *United Mine Workers*, 190 F.3d at 554; *Auchter*, 702 F.2d at 1155-56, 1158. *Compare* Defs. Br. at 40-41 (stating that the antimicrobial review is "among the largest [and] most complex" and "the rulemaking process continues to generate a considerable number of data submissions"), *with Int'l Chem. Workers Union*, 958 F.2d at 1148 (quoting OSHA statements that the "development of the standard[] . . . has proven more time consuming than anticipated" and that "it received more substantive comments . . . than it had anticipated and . . . [s]ubstantial additional staff time is required to analyze and respond to the issues raised" (internal quotation marks omitted)).

In cases cited by the FDA, courts excused delay of far shorter duration or when the agency, unlike the FDA here, had committed to a timeline, with dates certain, to finalize rulemaking. In *United Steelworkers of America v. Rubber Manufacturers Ass'n*, OSHA published a notice of proposed rulemaking on benzene and submitted a fourteen-month timeline for completion of the rule. This partially mooted the plaintiff's claim of the agency's failure to initiate, let alone complete, rulemaking. 783 F.2d 1117, 1119-20 (D.C. Cir. 1986). Similarly, the court excused a delayed revision to radon exposure limits because the agency had committed to finalizing the rule within two years. *Oil, Chem. & Atomic Workers Int'l Union v. Zegeer*, 768 F.2d 1480, 1484, 1488 (D.C. Cir. 1985). Moreover, the five years that had elapsed before the plaintiff brought suit was far shorter than the thirty-seven years at issue here and, unlike this case, where triclosan and triclocarban remain unregulated in antimicrobial products, in *Zegeer* a protective standard for radon was already in place. *Id.* at 1481-82.

Sierra Club v. Thomas is inapposite because the court found no statutory mandate to regulate strip mines as a source of fugitive emissions, whereas here, the FDA is required to evaluate all OTC drugs for safety and effectiveness. 828 F.2d 783, 798-99 (D.C. Cir. 1987) (noting also that "less than three years" and "little more than one year since the close of the public comment period" had elapsed). Finally, *Grand Canyon Air Tour Coalition v. FAA* does not support the FDA's argument. 154 F.3d 455 (D.C. Cir. 1998). The agency in that case had already issued a plan regulating aircraft noise over a national park, and there was no statutory requirement that the plan immediately achieve the restoration of natural quiet in the park, which was the relief sought by the plaintiff. *Id.* at 476-78 (D.C. Cir. 1998). In addition, the injuries alleged in *Grand Canyon* were aesthetic, and not health-related. *See In re Core Commc'ns, Inc.*, 531 F.3d 849, 855 (D.C. Cir. 2008) (noting that delays are "less tolerable when human health and welfare are at stake").

To credit the FDA's explanation that this complex rulemaking can only proceed in decade-long iterations as the science unfolds would justify granting the agency another thirty-seven years (or longer) to finalize the Monograph. Because every health-based standard is promulgated in the face of evolving scientific understanding, delay inevitably leads to more information for an agency to process, which lays the foundation for further delay. "[T]here is a limit to how long [the agency] may use these justifications to excuse inaction" on regulations that implicate public health. *United Mine Workers*, 190 F.3d at 554. We have reached that limit here.

B. Even Absent Explicit Deadlines, the FDA Has a Statutory Duty To Act With Reasonable Speed To Protect Public Health

In asserting broad discretion to conduct multiple, decades-long rounds of tentative rulemaking, the FDA presents this Court with a false choice between "scientific integrity" and

"haste." *See* Defs. Br. at 48. New medical knowledge is constantly emerging, but Congress expected the FDA to ensure that drug "products marketed serve the public with efficacy and safety." *See United States v. Article of Drug, Bacto-Unidisk*, 394 U.S. 784, 798 (1969) (internal quotation marks omitted). While the FFDCA does not contain explicit deadlines for agency review of OTC drugs, the expectation that rulemaking would proceed in increments of months or years, not decades, is discernible based on the 180-day deadline for the agency to decide on new drug applications, *see* 21 U.S.C. § 355(c)(1), and the agency's regulations setting time limits for submission of comments, reply comments, and new data regarding proposed OTC drug monographs, 21 C.F.R. § 330.10(a). *Cf. In re Monroe Commc'ns Corp.*, 840 F.2d 942, 945 (D.C. Cir. 1988) ("Delay is measured by a 'rule of reason,' informed whenever possible by discernible congressional expectations, respecting the pace at which proceedings should advance.").

In 1974, the FDA published its proposed regulation for triclosan and triclocarban. Even then, the agency recognized that these chemicals were potentially unsafe. 1974 Proposed Monograph, Ex. 3 to Wang Decl., at 33124 ("The suggestion of brain and splenic changes [resulting from triclocarban exposure] is of such importance that it cannot be ignored."). Subsequently, in the 1978 tentative order, the 1994 second tentative order, and in recent statements, the FDA has reiterated its belief that these products are likely ineffective, potentially harmful to human health, and implicated in the development of antibiotic-resistant bacteria. 1978 Tentative Monograph, Ex. 4 to Wang Decl., at 1233 ("[I]nfants should not be exposed to triclosan" due to "insufficient data to demonstrate whether it is the triclosan molecule or its metabolite(s) [breakdown product] that cause liver toxicity."); 1994 Tentative Monograph, Ex. 5 to Wang Decl., at 31427 (concluding that "with regard to safety for use as an antiseptic

handwash or health care personnel handwash . . . triclosan remains classified in Category III [insufficient evidence] for safety for long-term use"). On these facts, a court order requiring finalization of this regulatory process would not demean science or force the agency to act with undue haste.

The FDA's flexibility in structuring opportunities for public participation, *see* Defs. Br. at 47, does not excuse the length of delay in finalizing the regulation of triclosan and triclocarban. The notice-and-comment requirement was not intended to be a revolving door for endless rounds of reconsideration of tentative monographs. As the D.C. Circuit has noted, "[r]ulemaking proceedings would never end if an agency's response to comments must always be made the subject of additional comments." *Cmty. Nutrition Inst. v. Block*, 749 F.2d 50, 58 (D.C. Cir. 1984). The agency's regulations reveal an understanding that, regardless of developing scientific and technical data, there must be an end point to the review process. Within twelve months after the FDA publishes a tentative monograph, interested parties are permitted to submit additional information to support a condition of use excluded from the tentative order. 21 C.F.R. § 330.10(a)(7)(iii). After this time period, however, any new data submitted before the establishment of the final monograph "will be considered as a petition to amend the monograph and will be considered by the [agency] *only after a final monograph has been published*," unless the agency finds good cause to warrant earlier consideration. *Id.* § 330.10(a)(7)(v) (emphasis added). The reopening of the tentative monograph for further comments is thus an exception based on a finding of "good cause"; it is not the rule. The agency's discretion does not extend so far as to delay regulation indefinitely. As the D.C. Circuit noted in *Hayes*, once the FDA "elected to respond to its legislative directive by establishing the OTC drug review program, the APA imposed an obligation to proceed with reasonable dispatch." 818 F.2d at 895.

The evaluation of emerging science and competing comments does not justify extensive delay where the FDA has long been aware of its obligation to regulate over-the-counter drugs for safety and effectiveness. *See United Mine Workers*, 190 F.3d at 552-55 (D.C. Cir. 2001). Rather than providing the basis for further delay, citizen petitions filed with the FDA and the Environmental Protection Agency, *see* Def. Br. at 46 n.13, demonstrate the need to remove these chemicals from the market while the agency considers accumulating evidence of health risks. The "lack of a timetable does not give government officials carte blanche to ignore their legal obligations." *Cobell v. Norton*, 240 F.3d 1081, 1096-97, 1110 (D.C. Cir. 2001) (upholding lower court finding of unreasonable delay in government's duties to fulfill trust obligations to beneficiaries of Indian money trust accounts). The FDA's stated intent to finalize the rule "as soon as practicable," Defs. Br. at 3, is "no end-date at all." *United Mine Workers*, 190 F.3d at 556. This underscores the need for a judicially-imposed deadline.

C. The FDA's Delay Exposes the Public to Potentially Ineffective and Unsafe Drugs

Agency delay "is particularly disturbing" when "public health . . . [is] at stake." *Pub. Citizen Health Research Group v. FDA*, 724 F. Supp. 1013, 1022 (D.D.C. 1989). The unreasonableness of the FDA's delay is augmented by the fact that the agency itself "has acknowledged and credited scientific studies" that raise public health concerns regarding triclosan and triclocarban. *Id.* at 1019. In focusing on the uncertainty of relatively recent studies regarding the endocrine-disrupting properties of the chemicals, the FDA for the first time discounts its own statements of potential health risks including, but not limited to, reproductive and developmental harm. *See, e.g.*, 1974 Proposed Monograph, at 33124-25 (noting links between triclocarban use and brain, splenic, and testicular changes); 1978 Tentative Monograph, at 1231-34 (discussing the chemicals' potential toxicity to the liver);

FDA Letter to Markey, at 2 (citing numerous studies that suggest triclosan may interfere with the thyroid system and that raise "valid concerns about the effects of repetitive daily human exposure" to the chemicals).

The agency's acknowledgment of health risks posed by triclosan and triclocarban distinguishes this case from those cited by defendants. In *NRDC v. Fox*, where plaintiff requested faster promulgation of a pollution control standard under the Clean Water Act, the court found that other protective regulations ensured drinking water safety and that plaintiff did not show a significant public health risk from incremental water pollution in the interim. 93 F. Supp. 2d 531, 546 (S.D.N.Y. 2000) (citing three existing protective measures: memorandum of agreement between the city, state, and EPA on protection of water source; a separate city sanitary code; and the federal Safe Drinking Water Act). The court in *Oil, Chemical & Atomic Workers Union v. OSHA* emphasized that there was already a protective standard in place for hexavalent chromium. 145 F.3d 120, 122, 124 (3d Cir. 1998) (declining to find delay where agency projected issuance of a proposed rule within six years of the plaintiff's rulemaking petition). *Independence Mining Co. v. Babbitt* did not concern health risks; moreover, the plaintiff conceded that it did not need the mining patents in order to continue its mining operation and thus delayed agency action had no direct impact on mining jobs. 105 F.3d 502, 509-10 (9th Cir. 1997). Here, in contrast, the FDA's inaction has resulted in widespread marketing of products that the agency itself admits are potentially unsafe.

The FDA's continuing delay compounds the harm to plaintiff and the public. In the decades since the agency first proposed to regulate triclosan and triclocarban, products containing these chemicals have become widespread on the market. *See* Janssen Decl. ¶¶ 12-13. The implications of increased exposure to triclosan and triclocarban were foreshadowed by

the FDA's expert advisory panel in 1974, which raised concern about increased human blood levels of triclocarban resulting from "the possible future proliferation of [its] use in various OTC products, thereby increasing the possible total body burden." 1974 Proposed Monograph, at 33124. Thirty-seven years later, this concern has been validated. In a letter last year to Representative Markey, the FDA stated that "the majority of consumer antibacterial soaps contain triclosan or triclocarban as active ingredients," FDA Letter to Markey, at 6, and a study by the Centers for Disease Control and Prevention found triclosan residues in the urine of seventy-five percent of Americans over the age of six, Janssen Decl. ¶ 13. *See also* Defs. Br. at 20 (stating that FDA's drug advisory committee "also expressed concern about the societal consequences of the pervasive use of consumer antimicrobial products (not limited to drug products)"). Dr. Ganley, director of one of the FDA's drug evaluation offices, confirms this "increased exposure to topical antiseptic drugs" and the FDA's concern "about the potential long-term impact of these substances on human health and . . . the environment." Ganley Decl. ¶¶ 62-63.

Defendants attempt to reassure the Court that delay is not harmful because the agency has the power to order removal of drugs from the market if it deems that safety risks exist. For every example the agency presents of a drug that it has removed, however, there is an instance of a health threat that has escaped the agency's attention. Two million Americans were using the arthritis drug Vioxx at the time it was pulled from the market because of its link to heart attacks and strokes. Rita Rubin, *How did the Vioxx debacle happen?*, USA Today, Oct. 12, 2004, *available at* http://www.usatoday.com/news/health/2004-10-12-vioxx-cover_x.htm, Ex. 12 to Second Declaration of Vivian Wang ("Second Wang Decl."). Then-acting director of the FDA's Center for Drug Evaluation revealed that the agency had "been concerned and aware of

the potential for cardiovascular effects for . . . the last few years." *Id.* The weight loss supplement ephedra was banned in 2004, but the FDA had received reports years earlier of adverse effects from the drug, including death. *See* FDA News Release, FDA Acts to Remove Ephedra-Containing Dietary Supplements From Market (Nov. 23, 2004), *available at* http://www.fda.gov/NewsEvents/Newsroom/ PressAnnouncements/2004/ucm108379.htm, Ex. 13 to Second Wang Decl.; Letter from Sidney M. Wolfe, Director, Public Citizen's Health Research Group, to Michael D. Maves, Executive Vice President, American Medical Association (Jan. 17, 2002), *available at* http://www.citizen.org/Page.aspx?pid=2138, Ex. 14 to Second Wang Decl. And propoxyphene, an opioid typically used to treat mild to moderate pain, has been banned in the UK since 2005 because of its addictiveness and fatal toxicity at levels close to the therapeutic dose. *See* Press Release, Sidney M. Wolfe, Director, Public Citizen's Health Research Group, Delayed FDA Removal of Painkiller Propoxyphene (Darvon, Darvocet) From U.S. Market Has Cost More Than 1,000 U.S. Lives (Nov. 19, 2010), *available at* http://www.citizen.org/pressroom/pressroomredirect.cfm?ID=3221, Ex. 15 to Second Wang Decl. The FDA failed to respond to two citizen petitions in 1978 and 2006 to ban the drug, and only in late 2010 did the agency request that the manufacturer withdraw the drug. *Id.* The FDA's power to remove dangerous drugs from the market does not refute plaintiff's claim here, substantiated by the agency's own reports, that triclosan and triclocarban are ineffective and potentially unsafe.

The health harms from delayed regulation are particularly unacceptable because the agency has consistently stated that these products are not effective. In its 1974 proposed rule, the FDA drug review panel discussed a "well-conceived study" demonstrating that triclosan-containing soap "has no activity against *Pseudomonas* [a class of bacteria] and undemonstrated

claimed in vivo activity against other potential pathogens." 1974 Proposed Monograph, at 33128. The agency has reiterated these findings over the years. *See, e.g.*, 1978 Tentative Monograph, at 1232 ("The [FDA] Commissioner concludes that clinical effectiveness in the prophylaxis and treatment of superficial pyrogenic infections of the skin has not been established."); FDA Consumer Update, Ex. 7 to Wang Decl. ("At this time, FDA does not have evidence that triclosan . . . provides extra health benefits over soap and water."); Ganley Decl. ¶ 77 (reporting that "there was not adequate evidence to show that consumer handwashes provide an extra benefit over plain soap and water").

The FDA attempts to downplay the consequences of delay by pointing to ostensibly insufficient evidence of health harm. In so doing, the agency sidesteps its nondiscretionary duty under the FFDCA to regulate OTC drugs not only for safety but also for efficacy. 21 U.S.C. § 321(p)(1); *id.* § 355(d)(5). The health risks resulting from the indefinite delay in regulating triclosan and triclocarban are especially unjustified because the agency has insufficient evidence of countervailing health benefits of using the products.

D. Claims of Competing Priorities Do Not Excuse the FDA's Delay

An agency's competing priorities must be balanced against the length of delay and risks to public health. *See, e.g., Cutler v. Hayes*, 818 F.2d 879, 898 (D.C. Cir. 1987) ("The deference traditionally accorded an agency to develop its own schedule is sharply reduced when injury likely will result from avoidable delay."); *Auchter*, 702 F.2d at 1157-58 ("Delays . . . are less tolerable when human lives are at stake."). The FDA's other duties do not excuse the length of its delay, particularly in light of the agency's own acknowledgment of the significant risks to public health resulting from widespread use of triclosan and triclocarban. *Cf. In re Int'l Chem. Workers Union*, 958 F.2d 1144, 1150 (D.C. Cir. 1992) (stating that despite competing demands

and limited staff, the agency's "asserted justifications for the delay become less persuasive the longer the delay continues"). "However many priorities the agency may have, and however modest its personnel and budgetary resources may be, there is a limit to how long it may use these justifications to excuse inaction in the face of the congressional command to act . . . ." *United Mine Workers*, 190 F.3d at 554; *see also Cobell*, 240 F.3d at 1096-97.

A court order compelling final action within ninety days is reasonable given that the FDA has itself identified finalization of the antimicrobial Monograph as a priority. *See* Ganley Decl. ¶ 43. The agency is not creating the rule from a blank slate—the FDA's tentative classification of triclosan and triclocarban as Category II and III products has been pending for more than three decades. Finalization of the Monograph would not entail wholesale re-focusing of agency resources because the rulemaking process has been in its penultimate stage for decades. The FDA has already convened multiple review panels and spent thirty-seven years evaluating triclosan and triclocarban. *See* Ganley Decl. ¶¶ 39-41. Because the agency has consistently expressed concern regarding the chemicals' potential harm to human health—accentuated by the increasing prevalence of these products on the market, s*ee* FDA Letter to Markey, at 6; Ganley Decl. ¶ 62—and because the agency need not start from scratch to complete this regulation, the existence of other agency priorities does not warrant further delay.

The FDA states that ninety days will not provide sufficient time to finalize the Monograph, but offers no alternative timeframe for the court's consideration. In its semiannual regulatory agenda, the agency did not list an anticipated date for publishing notices of proposed rulemaking on antimicrobial products for use by healthcare professionals and food handlers, let alone a date for issuing final rules. 75 Fed. Reg. 21781, 21793 (Apr. 26, 2010). Given the

agency's continuing refusal to commit to a date certain for finalizing the Monograph, a judicially-imposed, short-term deadline is both appropriate and necessary.

E. The Agency's Delay Prejudices NRDC

The FDA's delay deprives plaintiff of its right to prompt, reasoned agency regulation of potentially harmful substances. While the agency has discretion as to how it regulates triclosan and triclocarban, it cannot effectively refuse to exercise that discretion after decades of delay. *See Independence Mining Co.*, 105 F.3d at 507 n.6. NRDC's request for relief is limited—plaintiff does not ask the agency to reach a particular conclusion in the final Monograph, only that the FDA finalize its rulemaking process.

The direct result of FDA inaction is the widespread marketing and use of products containing triclosan and triclocarban—a de facto classification of the products as Category I drugs that are safe, effective, and not misbranded. The absence of a final Monograph prevents NRDC and other interested parties from challenging the merits of the determination that these products should be permitted on the market. *Cf. Am. Broadcasting Co. v. FCC*, 191 F.2d 492, 501 (D.C. Cir. 1951) ("Agency inaction can be as harmful as wrong action. The [FCC] cannot, by its delay, substantially nullify rights which the [statute] confers, though it preserves them in form."). In choosing not to finalize the Monograph, the FDA has insulated from challenge its decision, in practice, that the products are safe and effective.

Defendants misconstrue NRDC's argument regarding the ruling of *Cutler v. Kennedy*, 475 F. Supp. at 838, which invalidated an FDA regulation permitting the marketing of Category III drugs after the issuance of a final monograph. *See* Defs. Br. at 48 n.14. NRDC does not claim that the FDA's current regulation regarding testing of Category III drugs is facially invalid. Rather, plaintiff argues that the extraordinary length of the agency's delay

effectively upends the statutory structure. If an OTC drug does not meet the agency's safety and effectiveness standards, it must undergo premarket clearance as a "new drug" and the manufacturer must submit "substantial evidence" in support of the application. *See* 21 U.S.C. § 355(d)(4)-(5); *Kennedy*, 475 F. Supp. at 852. The FDA has tentatively classified triclosan and triclocarban as Category II and III drugs for decades. *See supra* section II.C; *infra* section II.F. The agency's delay in finalizing the Monograph does not affirmatively sanction the continued proliferation of triclosan- and triclocarban-containing products, but absent evidence establishing the drugs' safety and effectiveness, the outcome is the same: It functions as an "assault on the premarket licensing scheme" of the FFDCA. *Kennedy*, 472 F. Supp. at 854.

NRDC does not seek to circumvent the process for notice and comment on the tentative Monograph. As discussed above, the statute and regulations envision that there must be an end point to rounds of revision; otherwise, no agency could ever take final action. The agency's argument flips the protective mandate of the FFDCA on its head. The default position under the statute is to remove products from the market unless their safety and efficacy can be proven. Had FDA finalized the Monograph after the 1994 tentative rule, triclosan and triclocarban would be eliminated from commerce because the former was classified as Category III for safety and effectiveness and the latter as Category III for effectiveness. The agency would be able to continue analyzing the "complex[]" and "evolving nature of the science" underlying the Monograph, Ganley Decl. ¶ 74, but absent a finding that the products are safe and effective, they should not remain on the market while the FDA continues its review of the scientific evidence.

F. The Court Need Not Find Agency Impropriety To Hold FDA's Delay Unreasonable

Agency impropriety is not a necessary component to a finding of unreasonable delay. *See In re Core Commc'ns*, 531 F.3d at 855. For decades, the FDA has credited scientific studies demonstrating significant health harms of triclosan and triclocarban, including liver toxicity, hormone disruption, and the development of antibiotic-resistant bacteria. *See, e.g.*, Janssen Decl. ¶¶ 20-26. The agency's inaction permits these products to be marketed widely despite their tentative Monograph status as Category II and III ingredients—unsafe and ineffective. *See* 1974 Proposed Monograph, at 33115 (designating triclosan and triclocarban as Category II ingredients when used in certain health-care personnel products, and as Category III when used in antimicrobial soap); 1978 Tentative Monograph, at 1227, 1229-30 (adding Category II designation for triclocarban in skin wound cleanser formulations other than bar soap); 1994 Tentative Monograph, at 31436 (designating both chemicals as Category III ingredients). This is an abrogation of the agency's statutory duty to protect public health by reviewing OTC drugs for safety and effectiveness. *See* 21 U.S.C. § 355(a), (d), (e); *id.* § 393(b)(2)(B); *Hayes*, 818 F.2d at 895. Judicial intervention is necessary and the relief that NRDC seeks is appropriately limited—finalization of the Monograph that is thirty-seven years in the making.

CONCLUSION

The FDA's continued delay in finalizing the Monograph flouts its statutory duty to ensure that all drugs are effective and safe. *See Hayes*, 818 F.2d at 895. Although "technical questions of health regulation are not easily untangled . . . [a]t some point, [the court] must lean forward from the bench to let an agency know, in no uncertain terms, that enough is enough." *Farmworker Justice Fund, Inc. v. Brock*, 823 F.2d 613, 627 (D.C. Cir. 1987). In this case, the agency's delay has permitted indefinite marketing and sale of products containing triclosan and

triclocarban, contravening its mandate to protect public health and despite the agency's own statements that the products are ineffective and potentially unsafe. For the reasons set forth above and in its opening papers, plaintiff urges the Court to grant its motion for summary judgment, deny defendants' motion for summary judgment, and compel the FDA to finalize the Monograph for triclosan and triclocarban within ninety days of entering judgment.

Respectfully submitted,

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